



# Who Should be Blamed for the Chaos in Chinese Food and Drugs Market?

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# **Who should be blamed for the chaos in Chinese food and drugs market?**

**Yanan Mo**

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## **Drugs:**

### **Introduction of development of drug evaluation in China**

#### *Development of Drug evaluation in China*

The Drug evaluation system in China has been defined by three major stages: initiation stage, development stage and establishment stage.

The initiation stage started in 1949 when the People's Republic of China was founded and ended in the 1970s. The landmark event was the joint publication of Draft Regulations for New Drug Products by Ministry of Health and Ministry of Chemistry and Industry. That was the first time when the evaluation of new drug products was regulated by certain laws. In 1979, the Ministry of Health and State Drug Administration jointly issued a New Drug Administration Law, which includes detailed explanations about the definition of new drug, the classification of a new drug, and the requirements of the data and clinical trials for new drug evaluation. The Ministry of Health was in charge of new drug evaluation and approval according to this law. However, the review science, regulatory procedures and related documents were not well established. As a result, the overall review process was not standardized.

The development stage started in the 1970s and ended in the 1990s. The landmark event was the implementation of the Drug Administration Law of the People's Republic of China in 1984. This

new law requires that rigorous monitoring and regulation be implemented for a new drug application. According to the law, no clinical trial can be started until all required documents and samples are submitted to and approved by the health regulatory agent at the province level or above. Before a new drug is marketed, the results of relevant clinical trials must be reviewed by an advisory committee and an approval letter with a registration number from the Ministry of Health must be obtained. To make the drug evaluation and approval process more efficient, the Ministry of Health has established a new office, Office for Drug Evaluation, in 1986 to be specifically responsible for drug evaluation. In 1995, this new office developed into an independent center, Center for Drug Evaluation (CDE). Despite the formation of the CDE, the main body of drug reviewers was the advisory committee at that time. When a new drug application was submitted, CDE was only responsible for randomly selecting the members of the advisory committee with the appropriate background from a database of experts for drug review. Those selected members would form a temporary advisory committee for this specific new drug and have meetings twice a year to discuss the review.

Starting from the 1990s, the drug evaluation system in China went into the establishment stage. Since the establishment of the State Drug Administration (SDA), Drug Administration Law of the People's Republic of China has been amended by SDA to further standardize the drug evaluation process. During this stage, the main body of drug evaluation shifted from the external advisory committee to the internal reviewers in CDE. CDE reviewers will evaluate all the applications first. If there are challenging issues based on preliminary review, CDE will organize an advisory committee meeting monthly to have a consulting discussion with experts in the relevant areas before making the final approval decisions. For those applications that do not contain controversial issues, CDE directly makes the final decisions. This standard evaluation

process has improved the review efficiency dramatically. In March 2003, SDA was renamed as the State Food and Drug Administration (SFDA) after food regulation was added to the function of SDA.

### *Standard Procedure for Drug evaluation in China*

Currently, there are five types of drug registration application in China: New drug application, generic drug application, imported drug application, supplemental application and renewal application. For the first three types of application, there are two major stages that are under regulation in China: application to initiate clinical trials (including bioequivalent trials) and application to market or import a drug. According to the Drug Administration Law, approval by SFDA is required before clinical trials can be conducted in China or new drugs can be marketed in or imported into China. The detailed application procedure and review process for these two stages are outlined in the 2007 version of Drug Registration Regulations. For supplemental application, the review process will depend on the magnitude of change in the product and the specific application documents. Clinical trials are required if necessary. For renewal application, each approved drug should be re-evaluated after 5 years and the renewal approval will depend on whether the post-marketing data suggest serious drug safety issues or not during the last 5 years. Overall, the review processes for these applications in CDE are similar to those implemented by US FDA (Li, 2003). There are review teams that are made of reviewers with expertise in different disciplines. The review team is responsible for evaluating whether the submitted data and documents support the safety and efficacy of the new drug as indicated. During the review

process, reviewers may interact with external experts and the drug developers to reduce the uncertainty about the drug's safety and effectiveness based on the submitted information.

The final decision for approval will be based on the risk/benefit balance for a specific indication after all the submitted information for the new drug is integrated during the drug evaluation process. For new molecular entities that are developed for serious or life-threatening diseases or diseases for which there is no available treatment, there exists fast track evaluation to accelerate the evaluation process (Yin, 2006). But based on the short history of twenty-five years (from 1984 to 2009) and the large number of applications (Figure 1, obtained from the CDE's internal annual report, not published), the drug evaluation system in China is different from any other countries'. It has its own characteristics with the quality control of the review, open-minded review, promoting research within CDE and integrating the post-marketing review.

### **What's going on in SFDA?**

Since many adulterations in drugs had happened so frequently these years, the public trust for SFDA declined day by day. What's going on in SFDA? Why hadn't it perform its authority to secure the safety use of drugs for the public as it should have?

#### ***SFDA is eroded by the corruption.***

In 2007, China's former drug and food safety watchdog chief, Zheng Xiaoyu, was executed after being found guilty of corruption and dereliction of duty. He was convicted of taking bribes worth some 850,000 USD from eight companies. After three years, another 6 officials from SFDA were accused of the guilty of corruption. What are the reasons for endless corruption?

### *same interest sharing*

The corruption cases mentioned above is nothing but in the approval process of drugs, medical devices or vaccine, etc. The overlapping characteristic of those is that the officials aligned with the companies, shared the same interest for making money regardless of the benefit of the public.

In the case of Zheng Xiaoyu, he abused his authority of approval, which resulted more than 10,000 drugs got approved within each year. In western developed countries, this amount of approval cost dozens of years.

Medical device, according to the regulatory guideline for medical device, should re-approve after 4 years sales in market for improvement according to the market feedback during the 4 years.

Different from drugs, medical devices doesn't enjoy as long market life cycle as drugs, the one year for approval will cost almost one thirds of the product life cycle. Some medical devices companies took illegal action to get the approval for preemption of the market share. Holding the authority of approval, SFDA became the primary target for public relation by the companies. As long as the officials shared the same interest with the companies, they could smooth the approval process for the medical devices.

### *Who monitor the behavior of SFDA?*

Since the lack of monitoring, SFDA's authority was abused. According to a chief deputy of Henan Medical oxygen Generator Company, SFDA carried two different kinds of criteria during the regulation of medical oxygen generator equipment. One kind of criteria is a seemly flawless and restrict GMP approval progress, the other criteria is equal to no criteria which means the



equipment can be sold without any certification or approval. Which criteria will the SFDA carry towards to each company is related to the relationship between the company and SFDA.

Also, no regulation restricts the performance of SFDA. In recent years, adulteration in drugs happened quite frequently. The related pharmaceutical companies had been punished, but it was hardly heard that related SFDA officials were punished. Even if the related officials were removed from the former position, after several months or years, they could recover their former positions or transform to other equivalent positions. Neither regulations nor restrictions towards the performance of SFDA officials lead to the abuse of authority.

#### *The gap between SFDA and US FDA*

Since the corruption in SFDA occurred so frequently, the society calls for revolution on monitoring SFDA. In fact, since the SFDA was established in 1998, it designed the regulation according to FDA. However, after 13 years, the effect the SFDA had made seems far from FDA.

US FDA is centralized, but independently operates. FDA regulates food and drug for both effect and side effect. It has strict regulation in research and development, clinical trials, manufacture and sales, and the regulatory officials have standardized professional background.

SFDA is decentralized, the administration and human resource are all appointed by local authorities. Thus, the missions are fragmented, and the professional level of officials differs between each province and city.

In addition, the sample test were run by FDA, rather than submitted by companies, the results would be transparent. The sample test results are submitted by the companies in China, so there might be many side effects for this solution.

Comparing the monitoring pattern, US FDA will pay much attention before the market to make sure the safety use by the consumers. In contrast, SFDA pay more attention on the punishment of problems occurred during the market sales.

Anti-corruption: In 1992, the US passes the Generic Drug Enforcement Act which authorizes FDA debarment right for any government officials, companies or individuals who intend to get approved by illegal ways. If someone bans the regulatory, he or she will face up to 1000,000 USD punishments. In addition, the information will be published on the FDA website for public notification. The debarment right doesn't aim to punish, it is set to make sure the vanishing of corruption in FDA. The regulation doesn't stop from the market entry of the products. The companies have to report the side effects which haven't been recognized during the clinical trial to FDA on a regular basis. FDA will make related action according to the report. The effective regulation system of FDA makes it as a mentor for pharmaceutical companies to improve the quality of products and development of research. SFDA should learn from the experience of FDA to improve their performance.

### **Other reasons**

Besides, in order to analysis the other causes of the current problems with SFDA, we need to look backward to the initial establishment of SFDA.

In April 1998, SFDA was established as a vice-ministry level institute, combined with former State Administration of Medicine of China, State Administration of Chinese Traditional Medicine of China, and Drug Administration bureau under Ministry of Health. What needs to be clarified is that the former State Administration of Medicine of China played a role of

management of pharmaceutical market in China, which is similar to what China National Pharmaceutical Group does today. (China National Pharmaceutical Group (SINOPHARM) is the largest pharmaceutical company in the world's most populous nation. The company researches and develops, manufactures, distributes, and markets medicine and other healthcare products. SINOPHARM manages factories, research laboratories, traditional Chinese medicine plantations, and marketing and distribution networks that extend throughout the country. It also has 10 subsidiaries and a number of major joint ventures. The company also runs about a dozen retail pharmacy chains. SINOPHARM, which has operations in Africa, France, Germany, Hong Kong, the US, and Vietnam, was formed in 1998. The Chinese government controls the pharmaceutical firm.) Affiliated to State economic and trade commission, the State Administration of Medicine of China was vice- ministry level and it was in charge of western medicine. The traditional medicine was in the charge of State Administration of Chinese Traditional Medicine of China. Prior to 1998, the administration and regulation of medicine was responded by Drug Administration bureau under Ministry of Health, which had lower level than the other two vice-ministry level institutes. For this reason, the state Administration of Medicine had the predominating authority in the reorganization revolution, which run the management and the interest of its subsidized pharmaceutical companies, which means the former regulated one predominated the former regulating one in the process of the newly established SFDA. In the new SFDA, the former State Administration of Medicine of China took up most of the positions, the former president of State Administration of Medicine of China Zheng Xiaoyu, who was the former director of a pharmaceutical company became the director of SFDA. In fact, the contradicted problem was even more severe in local governments. In many provinces and cities, the former directors of pharmaceutical companies took charge of local FDA, according to the

information from retired officers in SFDA. Thus, in the very beginning of the establishment of SFDA, how to separate the monitoring and management became a huge problem.

### *The dysfunction of central and local FDA*

Another main reason for the current chaos is that the central SFDA holds the approval authority but lacks of effective monitoring the local SFDA.

Since the establishment of SFDA, Zheng Xiaoyu advocated the policy which will change former localized approval criteria into national standardized criteria and thus held backward all approval authorities from local FDAs to central SFDA. Meanwhile, SFDA shifted all the responsibility of supervision to local FDAs. According to the human resource information from SFDA, the supervision bureau only contains five officers. It'll be mission impossible for these five people to deal with the supervision of the whole nation. The segregation of approval authority and supervision and the isolation of central and local SFDA led to the hidden danger afterwards. In theory, if the local FDAs report the side effects timely to the SFDA, it wouldn't hurt that much. But the SFDA had lost the control of local FDAs, which weakened its voice. The decentralization, in fact, starts from province level towards local areas. In the current system, if a pharmaceutical company performed against the regulations, SFDA have limited influence on the punishment decision under the pressure from the local FDA. One example can convince the public for this fact is that SFDA released three adulteration issues on the Chinese version website on March 23rd (news weren't release on the English version website). In the news, SFDA alerted that the three kinds of fake medicine were put on the shelf without getting approved, and notified the public avoid buying these three fake medicines. Besides that, SFDA didn't mention any action it will take to punish the related pharmaceutical companies.

From the other side, the local FDAs, they lack of reasonable income from approval application fees, which pushed them have to rely on the illegal tribute from the pharmaceutical companies under its supervision.

### *The distorted GMP policy*

Another policy Zheng Xiaoyu advocated was the GMP certification. Since 2004, the companies cannot manufacture without the GMP certification, which originally aimed to improve the quality control of manufacture and thus eliminated some small-scale, low-capacity pharmaceutical factories from the market. The hidden danger of central and local's segregated authority had been revealed that many companies got the GMP certification through bribery which was definitely cheaper and more effective than the investment on upgrading the manufacture lines. The GMP approval team was comprised by regulatory officers rather than scientific professionals, which left the approval process an skin-deep investigation. The loose supervision of local FDA had left the space for fake medicines leaking into the market.

### *Problem generated by Generic drugs*

Since almost all the approval applications are from generic drugs, the number of application is more than 10,000 each year. In contrast, USFDA faces about 200 companies' application for dozens of new drugs each year. Dozens of companies applied for the same generic drugs, which company can get approved depends on nothing but whether it can get approved prior to the others. The difference between companies is less important than their relationship with SFDA, which left the space for bribery. The limited number of reviewers in SFDA will face thousands

of companies' thousands times of lure, they can hardly prevent bribery without effective monitoring.

#### *Lack of follow-up reports system*

The 23th WHO conference pointed out that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being. Thus the public should have the right to know the adverse event of any drugs in the market. In the US, the adverse event reporting is collected from two reporting system, the compulsive reporting system for pharmaceutical companies and Med Watch voluntary reporting system. Periodic reports, follow-up reports and updating information gathered in the market are required to report to FDA on a quarterly basis, which provides the public timely safety information.

In Drug Law of China, it says the manufacturers and distributors should report to local FDA for any adverse effect of drug use. And the local FDA then reports to SFDA, Ministry of Health. But in recent adverse event issues, the local FDA released the related reports only after the issue had been the hot spot of the public through the reporting from the media. There exist several problems. Firstly, the pharmaceutical companies held back all the first-hand adverse event information from the market. For the sake of the interest of company, they lack of the incentives to publish the adverse event to the public. Meanwhile, the number of fake medicine and the number of adverse event are listed as performance evaluation for local FDA, thus local FDAs have no incentives to report the relative information to SFDA. The center for adverse event under SFDA is underemployed and lack of IT network which can catch timely information. All of the above have made it very difficult to keep the public aware of the timely information about safety use of drugs.

## **Safety use and adverse event issues**

### *Labeling and instruction issue*

The proper use of drugs cannot live without the proper labeling and instructions. Writing labeling and instructions are the behavior of companies to provide information for its products, which is usually considered as a way by which the company can induce the consumer to purchase the products. Consumers purchase drugs especially OTC drugs according to the labeling and instructions. Without proper and effective regulation, the company might set the labeling and instruction for sake of the interest, which may mislead the consumer by exaggerating the advantages while hiding or fading the adverse side of the drugs. Thus, the regulation of labeling and instructions has become one of the most important parts of SFDA's missions.

### *The clindamycin and Sibutramine issues*

According to the Provisions for Drug Insert Sheets and Labels of China, the outer label of a drug shall indicate such information as the adopted name in China, ingredients, description, indications or functions, strength, dose and usage, adverse reactions, contraindications, precautions, storage, production date, batch number, expiry date, approval number and manufacturer. Where indications or functions, dose and usage, adverse reactions, contraindications and precautions cannot be fully noted, main information plus a "See drug insert sheet for details." notice shall be indicated. However, SFD seems unable to make good use of the information. For example, in 2003, the adverse event of clindamycin had been reported to

SFDA for quite a long time. However, no further actions were taken preventing further side influence. Another example is the recall issue of Sibutramine. According to the news on Shanghai Daily Nov 1st, 2010, the Chinese government announced on October 30th a recall on weight-loss drugs containing "sibutramine." In China, 15 pharmaceutical products contain this active ingredient, including Qumei capsules, which account for half of the diet drug market in China. The recall order was issued by China's State Food and Drug Administration (SFDA), which followed the US FDA's request made on October 8th that sibutramine products should be withdrawn throughout the United States. The SFDA also banned the production, sale and use of all anti-obesity medications containing sibutramine, based on US FDA's review of large-scale trials which proves that sibutramine may increase the risk of high blood pressure and cardiovascular disease. Sibutramine was licensed for pharmaceutical use by the US in 1997 as an anti-obesity drug and was approved by the SFDA in China in 2000. According to SFDA's adverse drug reaction reporting data, from 2004 to 2010 Chinese hospitals received 298 reports on the negative side effects of using sibutramine, which included symptoms of cardiopalmus, constipations, dizziness and insomnia. The Taiji Group, which produces Qumei, said its sales revenue exceeded five billion yuan (US\$750bl) since the product went on sale in China in 2000.

The main reason for recall is that sibutramine was proved by the SCOUT study that contains more risk of cardiovascular events than its anti-obesity effectiveness. The SCOUT study showed a higher rate of cardiovascular events such as heart attack and stroke in obese and overweight patients using sibutramine than in patients managing their weight through exercise and diet alone. The public in China felt very disappointed with SFDA, since SFDA didn't do any risk analysis for this drug by itself. The announcement from SFDA came even later than the recall by the company following the result of SCOUT was released by foreign health authorities.



SFDA should have proactive effect, but they stand behind all of the issues, which had disappointed the public a lot. In fact, early in 2004, SFDA had already received approximate 298 cases for adverse events of Qumei. But no actions were taken. Up till foreign health authorities questioned the drug, SFDA began to reevaluate it. During this time, how many patients were influenced? Within the six years, any value information had been released? No. The announcement from SFDA was one month later than the companies' information release, which was unacceptable. As the gatekeeper for food and drug, SFDA should proactively perform its authority. The lagging action of SFDA would decrease its public credit. They should take the interest of the public as their priority as they should have.

#### *Problems in the review process*

In drug administration law of People's Republic of China, Article 31 states that production of a new drug or a drug admitted by national drug standards shall be subject to approval by the drug regulatory department under the State Council, and a drug approval number shall be issued for it, which the exception of the Chinese crude drugs and the prepared slices of Chinese crude drugs which where no control by approval number is exercised. The list of the Chinese crude drugs and the prepared slices of the Chinese crude drugs to be controlled by the approval number shall be compiled by the drug regulatory department under the State Council, in conjunction with the administrative department for traditional Chinese medicine under the State Council. A drug manufacturer may produce the drug only after an approval number is granted to it.

But the fake figures or data in the application materials is quite a lot for some of areas. Our review process is based on paper reviewing, rather than the actual inspection. Without the spot

inspection, the reviewers are unable to ensure the figures or data in the application comply with the actual quality of the drug or pharmaceutical companies, and it will be hard to tell whether the experiment can be repeated, whether the data can soundly support its conclusion.

In future, the spot inspection by the review team and the random inspection after marketing might be an effective way to improve the credits of approval granting.

### *The responsibility sharing of drugs' adverse events*

The adverse events of drugs are dependent to manufacturers, distributors, hospitals and governments, which leads a question of responsibility sharing. The administration instructions should perform its authority and responsibility to eliminate the risk of drug use as much as possible. If they fail to do that, they should also share the financial burden for the adverse events.

For example, in the clindamycin issue which has been mentioned, the pharmaceutical company failed to manufacture the products according to the manufacture process labeled on the package of the drugs. Also, the company didn't notify the consumer any warning of adverse event on its label. During the approval review, SFDA didn't find out the instructions of the drug, which had neglected its responsibility of scrutiny. What's more, when the adverse events were reported to SFDA in July, SFDA released the information to related province several days after, and published this news month after the event, which had strongly neglected its judgment authority. However, the primary responsibility should be taken by the company, SFDA should the secondary level responsibility for neglecting its regulation.

## **The historic issues accompanied SFDA**

### *Background for establishment*

Back to the reason for establishment of SFDA, prior to 1998, the pharmaceutical market in China was in a mass. Companies can manufacture drugs without any certificate or approval. The sales and purchase market were also out of control. Under the prevalence of kickback money between the pharmaceutical companies and hospitals, fake medicine began to enter the hospitals which were influenced by the market revolution. Since the ministry of health and hospitals had the relationship as father and son, the office of drug administration under Ministry of Health could hardly perform the regulation towards hospital. Under this background, the government initiated the SFDA establishment to restrain the chaos.

### *The conflict between different parties*

After ten years independent operation of SFDA since 1998, SFDA turn back under the monitoring by Ministry of Health since three years ago. SFD will go through another ten years' revolution. In April 1998, SFDA was established as a vice-ministry level institute, combined with former State Administration of Medicine of China, State Administration of Chinese Traditional Medicine of China, and Drug Administration bureau under Ministry of Health. At the very beginning, the composition of SFDA had planted unfavorable seed, since they combined three parties who had political conflicts with each other before the restructure. Thus it was very difficult for them to work in harmony during future work. Zheng Xiaoyu made main contribution to the establishment of SFDA, who send many officials abroad to study different Food and Drug Administration model. In the new established SFDA, there had 120 departments, in which three

parties respectively took up 80,30 and 10. The uneven distributed structure made the further cooperation even difficult.

### *Not the right time*

The new SFDA seemed that it hadn't chosen a suitable time to appear, since it overlapped with a most giant human resource revolution in government in 1998, most of the departments laid off officials. The establishment of SFDA and local FDAs seemed providing them with a new destination. Many officials in local FDA even didn't know drugs, who were laid off by other departments.

After Zheng Xiaoyu was sentenced to death, the national drug administration system began to change from bottom to up. The SFDA was combined into Ministry of Health; the primary positions in SFDA were replaced with officials from ministry of health. So were local FDAs.

### *Hospitals as the main circulation of drugs are out of control by FDA*

Since the establishment of SFDA, the separated regulations of hospitals and drugs had begun. The Ministry of Health was responsible for hospitals and physicians, while SFDA was in charge of administration of drugs and medical devices. This system was proved that had deep influence on the process of health care revolution.

Five years later, the minister of health Zhang wenkang was fired since he disguised the information of SARS at the initiative stage which delayed the timely actions to control the diseases' spread. Eight years later, Zheng Xiaoyu, the director of SFDA was sentenced to death for corruption.

Although, the administration of hospitals and drugs seemed separated since the establishment of SFDA, the separation was not thorough at the very beginning.

### *Hospital made medicine*

The problem was very typical on the “hospital- made medicine” issue.

So called hospital made medicine is the drug researched and developed, circulated by hospital, which can only be used within the hospital and cannot be circulated in the market. Since the establishment of SFDA, the hospital made medicine was down into a very embarrassing situation: it should be administrated by SFDA since it is drug, while it was developed and used within hospital which seemed that it should be regulated by Ministry of Health.

After the compromising between SFDA and Ministry of Health, hospital made medicine was administrated under both of the health authorities and was independent from other drugs.

It was rarely known by the public that meanwhile there had been more than 10,000 drugs approved by SFDA, almost same number of hospital made medicine was also approved by SFDA and Ministry of Health. The price of hospital made medicine is set independently from the market, usually the hospital made medicines are very expensive, which has become the invisible profits for hospitals.

## **Food**

### *2008 Chinese milk scandal:*

The milk scandal was a food safety incident in China involving milk and infant formula, and other food materials and components, adulterated with melamine, which appeared to have been added to milk to cause it to appear to have a higher protein content. By November 2008, China reported an estimated 300,000 victims, with six infants dying from kidney stones and other kidney damage, and a further 860 babies hospitalized. China's melamine milk adulteration crisis highlights the challenges that arise as large well-capitalized companies procure raw materials from a diffused supply chain of scattered small farmers and milk collection stations. As milk prices climbed sharply in 2007 and companies branched out into new territories, intense competition for raw milk supplies strengthened incentives to water down and adulterate milk. Effective food safety measures must account for incentives, the distribution of market power in the supply chain and market dynamics.

Although SFDA bears the name as State Food and Drug Administration of People's Republic of China, SFDA had no authority to regulate food in China. The regulation of food refers to Ministry of Health, Ministry of Agriculture and Ministry of Commerce. SFDA as a vice-ministry level authority had relatively weaker voice in the field of food.

In China, administration of food was segmented into different parts: the agriculture products are administrated by ministry of Agriculture, the manufacture of food is administrated by State Bureau of Quality and Technology Supervision, the circulation of food is administrated by State Administration For Industry and Commerce. The segmented management is inefficient, although the congress stated that the administration of food mainly rely on the segmented management method, assisted with the administration by category, in reality no administration by category has been used.

The coordination within different departments is a huge problem, which is the reason why the administration of food is still in a mess, so many governmental authority are assigned to commit in administration.

The administration of food in China is lagging; the authorities only take action after the issue happens. For example, after the poisoning milk issue was broadly published by the media, the relative departments send their representatives to the spot for inspection. They pay more attention to make up, rather than to prevention, which means no long-live, sustainable regulations are performed.

### *Clenbuterol Scandal*

According to ChinaDaily 2011 March, China has been hit by a fresh food scandal after the country's largest meat processor, Shuanghui, was forced to apologize when an illegal additive was found in some of its pork products.

Jiyuan Shuanghui, an affiliate of the Henan-based Shuanghui Group, was said to have bought pigs that had been fed with clenbuterol. The additive can speed up muscle building and fat burning to produce leaner pork – lean meat sells for a premium in China.

Clenbuterol is banned in China because if eaten by humans it can lead to dizziness, heart palpitations, profuse sweating, nausea, headaches, limb tremors and even cancer.

The Henan province conducted urine tests on 1,512 pigs in nine pig farms, with 52 pigs testing positive. Immediately, chiefs of animal husbandry bureaus in Mengzhou City, Qinyang City and Wenxian County received duty suspension notices. Another 27 officials in the province were in

police custody, sacked or suspended from duty. Also, the province intends to random test more than 1.63 million pigs in five counties and cities.

Meat products that are suspected of having been tarnished by the banned feed additive have already been taken off the shelves and meat confirmed to contain the additive have been destroyed, according to government officials.

While the China Meat Association tried to down play the possibility that tainted pork was widespread, many consumers will be avoiding pork for the moment. This pork scandal is definitely nothing new to the Chinese. There have been 18 outbreaks of food-related clenbuterol poisoning between 1998 and 2007, according to a report on the Shanghai Food Safety website. One person died and more than 1,700 others fell ill, the website said.

*The inspection is a muddle through rather than a genuine inspection.*

On the same day when the issue was published, an inspection group comprised of representatives from the security, Ministry of Agriculture, State Administration for industry and commerce, Ministry of Health and State Administration for Quality and technology Supervision immediately arrived at Henan Province to perform spot investigation and inspection.

And local government was required to inspect the positive pigs. The report submitted by local government that there were only six positive pigs out of 493 samples, which was contradicted with the results published earlier by the media. Thus, the accuracy and creditability of the inspection were questionable. The inspection only used one of the two tests of Clenbuterol,



which is the reason for the questionable inspection results, which also had exposed the neglecting responsibility of the related department.

Although the Chinese Government has made a lot of investment in the administration of food, the effectiveness seemed little. Each related authorities has their own inspection system, which had led to huge investment waste and the different criteria for the same kind of food made by different authorities confused the public and left the gap for illegal space for companies.

The companies are administrated by local authorities, who have little incentives to strictly regulate local companies. Since the taxes local companies submitted to local government had become the main profits local government receive sustainably.

### ***The reasons for unworkable food administration***

Firstly, China lack of a united national administration organization representing the interest of the public. The State Administration of Quality and Technology Supervision is in charge of the manufacture of food which performs the main role in food administration, doesn't work effectively, the main reasons are as followed.

#### ***Not Professional enough***

The administration of food needs profound scientific background. In US FDA, one third of the officials are scientists, their inspection work is scientific-based. In contrast, in related authorities, only few of the officials have scientific background, which makes the so-called inspection muddle through.

*Localization is poisoning.*

The administration of food should be a national organization. In China, the State Administration of Quality and Technology Supervision has many branches in each province, which is also governed by local government. Since the local government administrate local companies and local Administration of Quality and Technology Supervision, local government for the sake of interest, can easily disguise the illegal behavior of local companies. The main target for administration should be those companies with huge capacity, which have heavier responsibility for the food safety. However, many large-scale companies have become inspection-waive companies, local governments pay attention to small-scale companies.

*The information is not transparent.*

The transparency of information can not only keep the public known the latest food safety information, but also expose the organization under the monitoring by the public. Although, State Administration of Quality and Technology Supervision has become more and more transparent, the degree is not enough.

*The social environment is not ideal.*

The companies lack social responsibility, the society lack of credits and trust, and the corruption of government officials is severe. Under the current environment, even if State Administration of Quality and Technology Supervision become professional, get rid of localization, be responsible

and efficient, the effectiveness will not improve that much. So the revolution of State Administration of Quality and Technology Supervision is not the only thing we need to do.

### *Lack effective compensation policy*

The food safety cannot be regulated only by government, the social supervision is also very important.

Lack of compensation policy has weakened the social supervision power from several aspects:

Firstly, consumers lack incentives to supervise the food safety. According to the current consumer right pretention law, the consumers can get double compensation if their rights are attacked. In reality, the double compensation can hardly be realized, and consumer will give up since the double compensation is less than the time cost or transportation cost they will pay.

Secondly, the NGO or enthusiastic individuals have little incentives and support. Since they cannot get the support from their fights with illegal parties, their incentives are weakened. For example, there had a anti-fake hero, named Wang Hai who had done a lot against fake products. He changed his career since he could not get the support from the court. In all, the behavior of cheating is rarely under supervision of the public or the society.

Lack of punishment regulation will leave it alone with the irresponsibility of companies. Since the compensation for the consumer is relatively little, most consumers will not secure their own rights, which make the company pay even less attention to the interest of consumers. There is a trade-off between cost increase for food safety improvement and the cost for consumer compensation. If the cost for improvement of food safety is less than the cost for consumer

compensation, the companies will approach the cost for food safety improvement. Vice versa. The products exported to western country will pay for huge amount of compensation if the products attack the right of consumers, so the company will improve the product quality for exportation. However, they have no incentives to improve the product for domestic consumers since the cost for compensation is little compared with the cost for quality improvement.

In long term, under a healthy society environment, a professional, transparent national administration organization with the trust from the public can achieve effective administration of food. However, the policy revolution needs a long way to go. In short term, dealing with the corruption within related authorities might have some effectiveness, but the effectiveness is only temporary, which cannot sustain for long.

Currently, a pragmatic policy is to motivate social supervision, encourage the public with the compensation regulation. There is no clear law or regulations for compensation to consumers, but there also no upper limitation for mental compensation. Whether the related department can make good use of the sword depends on whether they are willing to take the responsibility. We appeal that the regulation department can increase the mental compensation so as to encourage the public to supervise the food safety.

### **Conclusion:**

Who should be blamed for the chaos in Chinese food and drugs market, the unhealthy environment, SFDA, State Administration of quality and technology supervision, or other authorities? None of the above should be blamed alone, and none of the above can get rid of the blame. The failure of food and drug administration is a one-factor issue; multi-factions interacted in a multiple way, which made it a complicated situation. There exist some chaos, but we should understand that it is not a piece of cake to regulate the drug and food safety for one fifth population in the world. Although several big food or drug scandals had made the administration authorities lost the trust from the public, we would still have confidence and call for the government to enhance the regulation towards food and drug safety. They are all century-long problem to choose centralization or decentralization, to use segmented management or systematic method, cost and effectiveness, long-term interest and short-term interest, the conflict between public and private interest, all of which have been touched in the food and drug safety issues. It will be a long to go to establish an all-around, sustainable administration system for food and drug for China. The rest of the world should leave her enough space to improve and develop.

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